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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/479,467 01/06/00 STERNBERG

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HM12/0731

EXAMINER

PARAS JR, P

ART UNIT

PAPER NUMBER

1632

DATE MAILED:

07/31/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/479,467

Applicant(s)

STERNBERG ET AL.

Examiner

Peter Paras

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5,9-11,15-17,21,22,25-32,42,49,74-77,82-84,88 and 89 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5,9-11,15-17,21,22,25-32,42,49,74-77,82-84,88 and 89 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 January 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 14.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Applicant's amendment received on May 16, 2001 (Paper No. 17) has been entered. Claims 1, 5, 9, 15, 27, 29, 31-32, 42, 49, 74, 76, 77, 82, and 83 have been amended. Claims 2-4, 6-8, 12-14, 18-20, 23-24, 33-41, 43-48, 50-73, 78-81, 85-87, and 90-92 have been cancelled. Claims 1, 5, 9-11, 15-17, 21-22, 25-32, 42, 49, 74-77, 82-84, and 88-89 are pending and are under current consideration.

Election/Restrictions

This application contains claims (88-89) drawn to an invention nonelected with traverse in Paper No. 13. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01. Please note that the arguments regarding the restriction requirement presented in Paper No. 17 have not been addressed as the restriction requirement was made final.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The previous rejection of claims 1, 5, 9-11, 15-17, 21-22, 25-32, 42 and 49 under 35 U.S.C. 112, first paragraph is obviated in view of Applicants claims amendments which recite *Caenorhabditis* LOV-1 genes.

Claims 27-32, 42, 74-77, and 82-84 as originally filed or amended are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a mutant *C. elegans* that comprises mutant a LOV-1 gene exhibiting a phenotype of defective mating behavior particularly in the male sensory behaviors response and location of vulva, does not reasonably provide enablement for transgenic *Caenorhabditis* nematodes comprising a vector encoding the nucleic acid sequence set forth in Seq Id 3, or any species of the nucleic acid sequence set forth in Seq Id 3, or any nucleic acid that encodes a mutated LOV-1 protein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The previous rejection of claims 27-32, 42, 74-77, and 82-84 is maintained for the reasons of record advanced in Paper No. 13 on pages 8-14.

Applicant's arguments have been fully considered but they are not persuasive. Applicants have argued that it would not require undue experimentation to introduce the *C. elegans lov-1* gene into a nematode of another *Caenorhabditis* species. Applicants assert that those of skill in the art are familiar with a variety of nematode species and manipulation of the genes in those species and recognize the relatedness among species of the genus *Caenorhabditis*. Applicants also have asserted that the references cited by the Examiner are not relevant because they describe unpredictability of transgenic behavior as it relates to unrelated inter-genera predictions, not intra-genus behavior of closely related species. See pages 12-19 of the amendment.

In response, the Examiner maintains that the instant specification does not enable the production of a transgenic *Caenorhabditis* species. The specification describes the production of *C. elegans* that have been mutagenized, wherein the mutagenized *C. elegans* are screened for a phenotype of interest, particularly a phenotype of defective mating behavior. That phenotype has been suggested to result from a mutated endogenous LOV-1 nucleic acid sequence; the mutations in endogenous LOV-1 are the result of exposure of *C. elegans* to mutagens rather than the creation of transgenic *Caenorhabditis* expressing LOV-1 or a variant of LOV-1. The specification has not presented working examples that correlate introduction and expression of a LOV-1 transgene into a *Caenorhabditis* and a corresponding phenotype that results from transgene expression. The art of transgenics is unpredictable with respect to expression of a transgene and the resulting phenotype. Expression of a transgene is directly dependent on the particular promoter and nucleic acid combinations used and the site of transgene integration in the host genome. The site of transgene integration is random, as such the resulting phenotype cannot be predicted. See Wall and Houdebine on page 12 of Paper No. 13. Furthermore, transgene expression in different species is not predictable and varies according to the particular host species and promoter/gene combinations. See Hammer, Ebert, Mullins, Kappel, Strojek and Wagner, and Wall on pages 12-13 of Paper No. 13. As the specification has not taught any transgenic *Caenorhabditis* one of skill cannot predict the phenotype resulting from expression of a LOV-1 transgene in any species of *Caenorhabditis*. Additionally, methods of using transgenic *Caenorhabditis* are not enabled because the

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transgenic *Caenorhabditis* are not enabled for the reasons of record. Finally, the specification has not provided any working examples that demonstrate identification of genes and regulatory factors involved in polycystic kidney disease using mutagenized *C. elegans*. The specification has failed to make a correlation between a nucleic acid sequence isolated by the same method and polycystic kidney disease. Accordingly, the rejection is maintained for the reasons of record.

The previous rejection of claims 1, 5, 9-11, 15-17, 21-22, 25-32, 74-77, and 82-84 is obviated in view of Applicants claims amendments which recite *Caenorhabditis* LOV-1 genes.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-11 as amended or originally filed are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The previous rejection of claims 9-11 is maintained for the reasons of record advanced in Paper No. 13 on page 17.

Applicants have amended claim 9 in an attempt to more clearly define the term "gene"

In response the Examiner maintains that the term "gene" is indefinite. There is no clear consensus definition in the art accurately delimiting the metes and bounds of the term "gene" particularly in view of alternative splicing and uncertainties surrounding the metes and bounds of cis-acting elements regulating mRNA expression. Although the claims as amended recite that the "gene" encode a LOV-1 protein the term "gene" encompasses more than just the LOV-1 coding regions. For example the term "gene" also encompasses intron/exon boundaries and promoter regions, which have not been defined by the claims. Accordingly, the rejection is maintained for the reasons of record.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, 7, 9-11, and 15-17 as amended or originally filed are rejected under 35 U.S.C. 102(b) as being anticipated by Wilson et al. The previous rejection is maintained for the reasons of record advanced in Paper No. 13 on pages 18-19.

Applicants have argued that Wilson does not teach the nucleotide sequence set forth in Seq Id 3. Applicants also argue that Wilson also does not teach the 3178 amino

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acid LOV-1 protein or any coding regions or any intron/exon boundaries of the LOV-1 genomic sequence. See the amendment on pages 26-30.

In response, the Examiner maintains that the Wilson sequence anticipates the claimed invention. First, Wilson has taught a nucleotide sequence that has 100% local similarity to the nucleotide sequence set forth in Seq Id 3. Claim 1 for example uses open claim language to recite a nucleotide sequence that comprises the sequence of Seq Id 3. As the sequence of Wilson and Seq Id 3 share 100% local similarity, the sequence of Wilson comprises that of Seq Id 3. Next, as the sequence of Wilson shares 100% identity with that of Seq Id 3, it is inherent that the sequence of Wilson encodes the same amino acid sequence as the amino acid sequence encoded by Seq Id 3. Further, as the Wilson sequence and Seq Id 3 share 100% similarity, the sequences will hybridize to each other.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The previous rejection of claims 1, 5, 7, 9-11, and 15-17 under 35 U.S.C. 103(a) as being unpatentable over is obviated as there was no motivation to combine the Hughes, Bargmann, and Wilson references. Particularly, none of the references taught

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a correlation between polycystic kidney disease and the nucleotide sequence set forth in Seq Id 3.

Applicants arguments are moot in view of the withdrawal the rejection under 35 U.S.C. 103(a).

Allowable Subject Matter

Claims 21-22, 25-26, and 49 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

No claims are allowed. Claims 21-22, 25-32, 42, 49, 74-77, 82-84 are free of the prior art of record because the prior art of record does not teach or suggest a transgenic C elegans comprising a nucleotide sequence encoding LOV-1 or methods of using the same.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is 703-308-8340. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Karen Hauda, can be reached at 703-305-6608. Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703)308-4242 and (703)305-3014.

Inquiries of a general nature or relating to the status of the application should be directed to Kay Pinkney whose telephone number is (703) 305-3553.

Peter Paras, Jr.

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ROBERT A. SCHWARTZMAN
PRIMARY EXAMINER